

RapiDx

Victoria VanderNoot, Ph.D.
February 25, 2015
Sandia MedTech Showcase

Brief Technology Overview – RapiDx

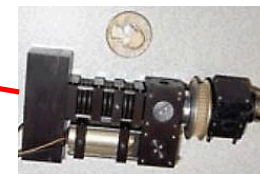
Rapid, Automated Point-of-Care System (RapiDx)

- Portable microfluidic *in vitro* diagnostic instrument for cancer and infectious disease biomarkers in human biological samples
- Point-of-Care diagnostics amenable to health clinics and field sensing applications
- Integrated miniaturized electronics, optical elements, fluid-handling components, and data acquisition software
- Portable, self-contained device.

Brief Technology Overview – RapiDx



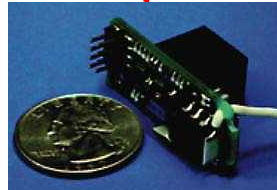
Disposable
Immunoassay
cartridge



Laser-
Induced
Fluorescence
Detector

Touch-
screen
LCD

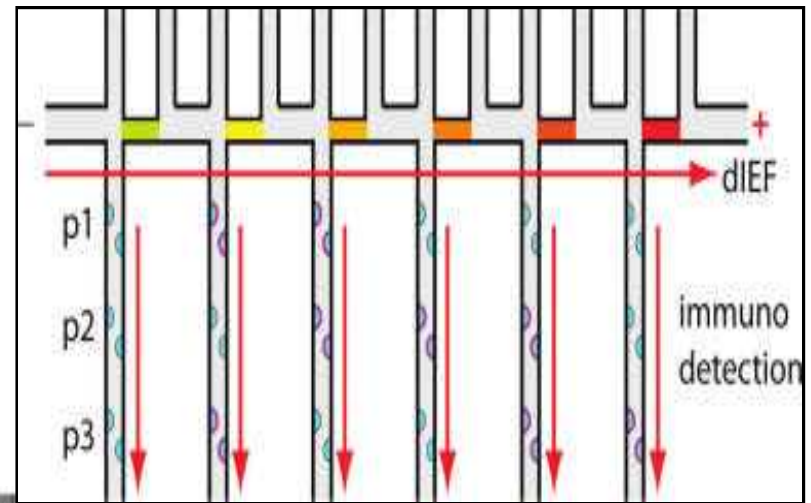
small footprint (8 in.)



High-Voltage
Power Supply / CPU

Underlying Technology

Disposable
Immunoassay
cartridge



Multidimensional analyses to yield high confidence and excellent discrimination

1st Dimension - digital Isoelectric Fractionation (dIEF)

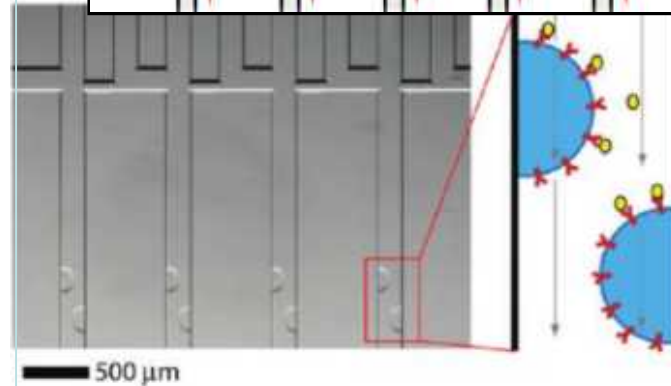
Reduces interferences

Less reliance on the quality/specificity of antibody

2nd Dimension – Immunodetection

Multiple detection spots can each exploit different antibody

Higher discrimination – unique patterns



TECHNOLOGY COMPARISON

Current Gold Standard is ELISA

- quantitative, specific, sensitive detection
- long incubation times (from 4 to 24 hours)
- multi-step fluid handling and significant technical expertise.
- Not suitable for immediate health assessment at the POC.
- Detection limits approach 1 pg/mL

RapiDx Microfluidic Diagnostics Technology

- Increased surface area-to-volume means faster antibody-antigen reactions.
- Smaller dimensions reduce consumption of expensive reagents and precious samples.
- Automated fluid handling can improve reproducibility, throughput and reduce required operator skill

**** RapiDx immunodetection sensitivity is one to two orders of magnitude greater than standard ELISA test kits.***

RapiDx *Benefits*

Effectiveness/Performance

- Increased Sensitivity
 - One-to-two orders of magnitude greater detection sensitivity than ELISA
 - Femtomolar concentrations – important for measuring physiologically relevant levels.
- Excellent discrimination since two independent modes of discrimination
 - Stringency of antibody may not need to be as high
 - Can make it work even when really good antibodies may not be available
- Versatility
 - Multiplex 1-20 finger prick blood samples
 - Wide range of sample types
 - Readily adapted to other clinical and medical detection problems
- Preserves biological sample in native state to provide excellent quantitative assay

Savings

- Space and power (small form factor)
 - Portable, self-contained, low power
 - << tabletop required
- Time savings
 - Microfluidics yields rapid (45 min.) sample in, result out
 - Read-out of a suite of routine tests during a doctor's visit
- Cost Savings
 - Small volumes = Decreased reagent costs
 - Minimal operator training = Labor cost savings

COMPETITIVE LANDSCAPE

	RapiDx	Enzyme Linked Immunosorbent Assay (ELISA)	RNA Expression Profiling, Quantitative Reverse Transcription - Polymerase Chain Reaction (qRT-PCR)	Mass Spectrometry (MS)
Specificity	✓	✓	✓	✓
Detection of Targeted Glycosylation	✓	Possible but challenging	X	✓
Improved Sensitivity	✓	X	✓	✓
Integrated Sample Preparation	✓	X	X	X
Protein Structural Analysis	X	X	X	✓
Rapid Workflow (45 min. sample-to-results)	✓	X	X	X
Operator Skillset (hands free analysis)	✓	X	X	X
Instrument Cost	\$	\$	\$	\$\$\$

REPRESENTS NEXT GENERATION DIAGNOSTICS

Centralized Laboratory

- Large instruments requiring certified operators
- 60-120 min. assay times
- Quantitative biomarker content
- Gold-standard methods



Point of Care: Clinician's Office

- Automated (integrated sample preparation)
- 5-45 min. assay times
- Quantitative biomarker content
- Multi-analyte panels relevant to complex diseases



Point-of-care: home use

- Simple to use
- 3-20 min. assay times
- Qualitative binary output
- Limited relevance to complex diseases



Current Development and Licensing

- Current license to Olmstead Engineering, LLC based in Ohio for detecting prostate cancer, breast cancer, pancreatic cancer and cancer of the head and neck
- Wide open for assorted applications
 - Readily adaptable platform (can be customer driven)
 - Selection of suitable antibodies